

DP Barcode : D228013
 PC Code No : 128847
 EEB Out : / /

OCT 7 1996

To: Cynthia Giles-Parker
 Product Manager 22
 Registration Division (7505C)

From: Anthony F. Maciorowski, Chief
 Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 000100-00740
 Chemical Name : Difenconazole
 Type Product : fungicide
 Product Name : Dividend
 Company Name : Ciba-Geigy
 Purpose : Review seed treatment use.

Action Code: 330
 Reviewer: Dennis McLane

Date Due: 11/14/96

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1 (A)			72-2 (A)			72-7 (A)		
71-1 (B)			72-2 (B)			72-7 (B)		
71-2 (A)			72-3 (A)			122-1 (A)		
71-2 (B)			72-3 (B)			122-1 (B)		
71-3			72-3 (C)			122-2		
71-4 (A)			72-3 (D)			123-1 (A)		
71-4 (B)			72-3 (E)			123-1 (B)		
71-5 (A)			72-3 (F)			123-2		
71-5 (B)			72-4 (A)			124-1		
72-1 (A)			72-4 (B)			124-2		
72-1 (B)			72-5			141-1		
72-1 (C)			72-6			141-2		
72-1 (D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur

P=Partial (Study partially fulfilled Guideline but additional information is needed)

S=Supplemental (Study provided useful information but Guideline was not satisfied)

N=Unacceptable (Study was rejected)/Nonconcur



2071207

EEB files

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71-1 (B)			72-2 (B)			72-7 (B)		
71-2 (A)			72-3 (A)			122-1 (A)		
71-2 (B)			72-3 (B)			122-1 (B)		
71-3			72-3 (C)			122-2		
71-4 (A)			72-3 (D)			123-1 (A)		
71-4 (B)			72-3 (E)			123-1 (B)		
71-5 (A)			72-3 (F)			123-2		
71-5 (B)			72-4 (A)			124-1		
72-1 (A)			72-4 (B)			124-2		
72-1 (B)			72-5			141-1		
72-1 (C)			72-6			141-2		
72-1 (D)						141-5		

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DP BARCODE: D228013

CASE: 008224
SUBMISSION: S508513

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/17/96
Page 1 of 1

EEB files

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 330 TECH-NEW F/F USE AMND
RANKING : 10 POINTS ()
CHEMICALS: 128847 Difenoconazole

32.8000%

ID#: 000100-00740 DIVIDEND
COMPANY: 000100 CIBA-GEIGY CORP
PRODUCT MANAGER: 22 CYNTHIA GILES-PARKER 703-305-5540 ROOM: CM2 229
PM TEAM REVIEWER: JAMES STONE 703-305-7391 ROOM: CM2 247
RECEIVED DATE: 06/27/96 DUE OUT DATE: 01/03/97

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 228013 EXPEDITE: N DATE SENT: 07/17/96 DATE RET.: / /
CHEMICAL: 128847 Difenoconazole
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 11/14/96
DIV : EFED	7/23/96	/ /	NEGOT DATE: / /
BRAN: EEB	7/24/96	10/2/96	PROJ DATE: / /
SECT:	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Are there any concerns for non-target organisms from
proposed seed treatment use on barley, oats and triticale?

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
228012	RCAB	07/17/96	11/14/96	Y	N	Y
228014	EFGB	07/17/96	11/14/96	Y	N	Y
228015	FHB/PMT-21	07/17/96	11/14/96	Y	N	Y

DP BARCODE: D228017

CASE: 014483
SUBMISSION: S508514

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/17/96
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 330 TECH-NEW F/F USE AMND
RANKING : 10 POINTS ()
CHEMICALS: 128847 Difenoconazole

1.5400%

ID#: 000100-00777 DIVIDEND 0.15 FS FUNGICIDE
COMPANY: 000100 CIBA-GEIGY CORP
PRODUCT MANAGER: 22 CYNTHIA GILES-PARKER 703-305-5540 ROOM: CM2 229
PM TEAM REVIEWER: JAMES STONE 703-305-7391 ROOM: CM2 247
RECEIVED DATE: 06/27/96 DUE OUT DATE: 01/03/97

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 228017 EXPEDITE: N DATE SENT: 07/17/96 DATE RET.: / /
CHEMICAL: 128847 Difenoconazole
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 11/14/96
DIV : EFED	7/23/96	/ /	NEGOT DATE: / /
BRAN: EEB	7/24/96	10/7/96	PROJ DATE: / /
SECT:	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

See instructions for ID # 100-740.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
228016	RCAB	07/17/96	11/14/96	Y	N	Y
228018	EFGB	07/17/96	11/14/96	Y	N	Y
228020	FHB/PMT-21	07/17/96	11/14/96	Y	N	Y

EEB REVIEW

Chemical: Difenoconazole

100 Submission Purpose and Label Information

Amendment to add directions for use on the following new crops: barley, oats, and triticale.

100.1 Submission Purpose and Pesticide Use

These products will be used as seed treatment to control fungus.

100.2 Active Ingredients

Three labels were submitted with different percent active ingredient for each product. The following lists the active ingredient for each product.

Product Name: Dividend

ACTIVE INGREDIENT:

[(2S,4R)/(2R,4S)]/[(2R,4R/2S,4S)] 1-{2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl}-1H-1,2,4,-
triazole.....32.8%

INERT INGREDIENTS: 67.2%

Total: 100.0%

Product Name: Dividend 0.31 FS

ACTIVE INGREDIENT:

[(2S,4R)/(2R,4S)]/[(2R,4R/2S,4S)] 1-{2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl}-1H-1,2,4,-
triazole.....3.15%

INERT INGREDIENTS: 96.85%

Total: 100.0%

Product Name: Dividend 0.15 FS

ACTIVE INGREDIENT:

[(2S,4R)/(2R,4S)]/[(2R,4R/2S,4S)] 1-{2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl}-1H-1,2,4,-
triazole.....1.54%

INERT INGREDIENTS: 98.46%

Total: 100.0%

100.3 Application Methods, Directions, Rates

The application rates are different in terms of product per CWT of seeds but not in the maximum amount of active ingredient applied. As shown below the rate for Dividend and Dividend 03.1

DP BARCODE: D228032

CASE: 014473
SUBMISSION: S508521

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/17/96
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 330 TECH-NEW F/F USE AMND
RANKING : 10 POINTS ()
CHEMICALS: 128847 Difenoconazole

3.1500%

ID#: 000100-00778 DIVIDEND 0.31 FS FUNGICIDE
COMPANY: 000100 CIBA-GEIGY CORP
PRODUCT MANAGER: 22 CYNTHIA GILES-PARKER 703-305-5540 ROOM: CM2 229
PM TEAM REVIEWER: JAMES STONE 703-305-7391 ROOM: CM2 247
RECEIVED DATE: 06/27/96 DUE OUT DATE: 01/03/97

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 228032 EXPEDITE: N DATE SENT: 07/17/96 DATE RET.: / /
CHEMICAL: 128847 Difenoconazole
DP TYPE: 001 Submission Related Data Package

CSF: N LABEL: Y
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 11/14/96
DIV : EFED 7/23/96 / / NEGOT DATE: / /
BRAN: EEB 7/24/96 10/7/96 PROJ DATE: / /
SECT: / /
REVR : / /
CONTR: / /

* * * DATA REVIEW INSTRUCTIONS * * *

See instructions for ID # 100-740

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
228031	RCAB	07/17/96	11/14/96	Y	N	Y
228034	EFGB	07/17/96	11/14/96	Y	N	Y
228035	FHB/PMT-21	07/17/96	11/14/96	Y	N	Y

FS is the same.

Barley

Product	Pro- duct Rate /CWT (fl oz)	A.I. Rate/ CWT (fl oz)	Diseases Controlled	Diseases Partially Controlled
Dividend	1	0.328	Barley Stripe General Seed Rots Fusarium Seed Scab Covered Smut	Take-All Common Root Rot Fusarium Root Rot Loose Smut
Dividend 0.31 FS	10	0.315		
Dividend 0.15 FS	10	0.154		

Oats

Product	Pro- duct Rate /CWT (fl oz)	A.I. Rate/ CWT (fl oz)	Diseases Controlled	Diseases Partially Controlled
Dividend	1	0.328	Loose Smut General Seed Rots	
Dividend 0.31 FS	10	0.315		
Dividend 0.15 FS	10	0.154		

Triticale

Product	Pro- duct Rate /CWT (fl oz)	A.I. Rate/ CWT (fl oz)	Diseases Controlled	Diseases Partially Controlled
Dividend	1	0.328	General Seed Rots	
Dividend 0.31 FS	10	0.315		
Dividend 0.15 FS	10	0.154		

100.4 Target Organism

(See table above)

100.5 Precautionary Labeling

"Environmental Hazards

"This product is toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters or rinsate."

"If treated seed is spilled outdoors or in areas accessible to birds, promptly clean up or bury to prevent ingestion."

101. Risk Assessment

101.1 Discussion

Dividend is registered on wheat (Hitch's review March 29, 1994) which is a large crop (59,089,470 acres) where barley (6,818,065 acres), oats (4,187,873 acres) and triticale (22,188 acres) are smaller (1992 Census of Agriculture). Therefore, this amendment will increase the potential treated area by 18.7%. The use rates for these crops are equal to the wheat rate. The same assumptions were used to determine the exposure for these crops as well. The following is excerpted from that review (Hitch, R. Mar 29, 1994):

"Difenoconazole is applied to wheat and barley seed. The maximum application rate for wheat is one fluid ounce of product per 100 pounds of seed and the barley seed maximum rate is one half ounce per 100 pounds for barley [This was increase in this submission to the wheat rate]. The product is 3 lbs of active ingredient per gallon resulting in a maximum residue on wheat seed 230 ppm."

"If we assume that farmers typically sow around 50 pounds of wheat seed per acre we can estimate a residue in soil. The 50 pounds of seed would contain 0.01 lb of active ingredient if one follows the maximum label rate. There are about 40,000 square feet in an acre so the application rate is 0.010 lb./ 40,000 sq. ft., or approximately 0.25 millionth of an ounce per square foot. Soil typically weighs about 80 pounds per cubic foot. We will assume that the difenoconazole stays in the top four inches. Therefore, in the top four inches of soil, we would expect a residue of about 10 ppb (0.25×10^{-6} lb a.i./23 lbs soil)."

This estimate for soil is low. The "Foods and Food Production Encyclopedia" (Considine. ed. 1982) reports in some cases that wheat is plant at a rate of 125 lbs/A and barley at 100 lbs/A. Therefore, barley residue would be double the above estimate or 20 ppb and wheat would be 25 ppb.

101.2 Likelihood of Adverse Effects on Nontarget Organisms

Risk to Aquatic Organisms

Risk to aquatic organisms is not expected. The GENEEC approach was used to estimate the EEC. However, four of the environmental fate values were not available. Three test results used are: soil aerobic metabolism, aerobic aquatic metabolism and photolysis. Because these were values unavailable default setting was used for these tests. The default settings assumes that the compound is stable and will not degrade. This insures that the EEC is not under estimated (pers. comm. R. Parker). To determine the Koc, the last item, a similar chemical fenbuconazole was used (pers. comm. P. Mastradone). Fenbuconazole has three Kocs for three different soils. The clay soil gave the lowest, Koc 2185, and the most conservative. The peak EEC was 140 ppt (see attached printout). The lowest acute toxicity value for fish and invertebrates is the 350 ug/L or ppb, for the rainbow trout LC50. The EEC/LC50 is $0.14/350$ or 0.0004. The lowest LOC is 0.05 for endangered species. Therefore, minimal acute hazard is expected. Chronic risk is more difficult to estimate. Chronic studies for both fish and invertebrates failed to meet guideline requirements but were scientifically sound. The early life stage study with fathead minnow did not fulfill the guideline requirements. The relative standard deviation for fish weight in one of the control replicates was unacceptable and control contamination was observed in two replicates. The MATC was $>8.7 < 19$ ug a.i./L. The invertebrate study did not measure the weight of the daphnids. These errors may have masked effects at lower levels. However the appears to be a adequate margin of safety in this case. The invertebrates are slightly more sensitive on a chronic basis than fish. The daphnia magna life cycle MATC is $>5.6 < 13$ ug a.i./L. The EEC/NOEC is $0.14/5.6 = 0.025$. The LOC for chronic effects is 1. Therefore the risk is expected to be minimal. However, as Hitch reports below an accidental spill could be difficult to manage.

"In the case of an **accidental spill** to surface water the high toxicity of difenoconazole to aquatic organisms and its high solubility of one 55 gallon drum of the product could theoretically contaminate a 60 million gallon lake with the LC50 for the trout, Onchorynchus mykiss. (Based on 55 gallon drum weighing approximately 520 pounds and consisting of about 32.8% active as accepted by EPA 6-11-93 for the product known as Dividend)."

Risk to Earthworms

Of the three labels submitted in connection with this submission one is Dividend, a 32.8% of the product. The excerpt from Hitch's review adequately address the effects on earthworms.

"Risk to Terrestrial Organisms"

"An earthworm study utilizing 14 days of exposure was submitted voluntarily by the registrant. It has not been evaluated by the Agency since it is a non-guideline study. The study results indicate that the LC50 is greater than 600 ppm. During a pilot study 100 percent mortality was observed at 1000 ppm. Even if we took the LC50 to be 600 ppm, it is thousands of times larger than the projected residue in soil of 10 ppb. No acute hazard is projected for earthworms.

However, as previously pointed out the seeding rates may be higher than used in this calculation. Never the less the highest expected concentration is 25 ppb rather than 10 ppb. This increase still does **not** change the conclusion of minimal acute hazard to earthworms.

Risk to Mammals

The lowest LD50, 505 mg/kg, is the rat test with difenoconazole 32.7% product. This formulated product is significantly more toxic than the technical which has an LD50 of 1453 mg/kg.

Minimal risk of mortality is expected for small mammals. The following calculations show the number seeds that would result in an LD50 dose for a meadow vole or 10,906 seed/LD50 (see calculations below). If this equals a risk quotient of 1, then the LOC risk quotient is 0.5 for acute toxicity or 5453 seeds. It is not likely that a vole would be able to find and eat this many seeds in one day. The calculations would not be expected to be significantly different for oats and triticale. Notice that the lowest LD50 is not with the active ingredient but the product.

Meadow vole and Barley

Information:

1. LD50 = 505 mg/kg of product
2. Bodyweight of a meadow vole = 0.046 kg (Davis, 1963)
3. Weight of a barley seed = 0.033 g
4. 10 fl oz. of product/100 lbs of seed = a conc. of 648 ppm of product.

$$10,906 \text{ Seeds/vole/day/LD50} = \frac{505 \text{ mg/kg (LD50)} * 0.046 \text{ kg (bodyweight)}}{0.033 \text{ weight of a barley seed} * 648/1,000,000}$$

Two chronic studies produced results less than the EEC of 230 ppm. First, the rat 2-generation reproduction (MRID#42090021)

showed systemic and reproductive NOELs of 25 ppm. There was a significant reduction in the body weight of F1 male pups at day 21 for 250 ppm (the next highest level). Also, the 250 ppm F0 females had reductions (statistically non-significant) in body weight gain which appear to be part of a dose related trend days 70-77 prior to mating, days 0-7 of gestation, and days 7-14 of lactation. Second, the 13-week feeding study with rats showed a systemic NOEL of 20 ppm (MRID#42090022). At the LOEL (200ppm) there was 10% decrease in body weight (as well as a negative trend in the feed consumption) and increases in absolute liver weights in both sexes appearing at 750 ppm.

Weigh loss for both adults and offspring can be expected for small wild mammals with diets containing concentration of 20 ppm or more. The expected concentration on seeds is 230 ppm. The LOELs were 200 and 250 ppm for the feeding and reproduction studies, respectively. Therefore, dose in the seed would be adequate. Exposure at a critical time may result in mortality. For example, small mammals feeding on treated seeds in the spring before regaining weigh loss in the winter are likely to have lower reproduction success. Also, survival of under weight young is likely to be lower. The reproduction study indicated that, "There was a significant reduction in the body weight of F1 male pups at day 21 in the 250 ppm group.". Weight loss would be expected to increase the stress of survival in the wild. For example, hunting for food and avoiding predators are activities not required under test conditions. Therefore, more energy is required to survive the stresses of the wild. Based on this risk is expected for small mammals.

Risks to Birds

As reported in the Hitch's review, "For terrestrial birds, the criteria for high risk concern is 1/2 the LC50 (Neither of the two avian reproduction studies were acceptable). The LC50 was 4760 ppm for the bobwhite (MRID 422451-03) making the risk criteria 2380 ppm. Because the highest concentration on seeds is 230 ppm, no acute risk is projected for birds." However, the mammal LD50 studies show that the product is significantly more toxic than the technical grade material. Therefore, before risk assessing is complete acute testing on the product is needed.

The bobwhite quail reproduction study NOEC was 125 ppm. The LOEC was 625 ppm. At this level egg production, embryo viability, and number of offspring were reduced. For the mallard duck study egg shell thinning occurred at the same level which was also the LOEC. Both studies are supplemental, therefore, the deficiencies may be masking effects at the lower concentrations. An avian reproduction risk is expected. The concentration on the seed will be 230 ppm and the NOEC is 125 ppm for both species. This provides a risk quotient of 1.84. This exceeds the level of concern (LOC) of 1 for chronic studies and the acute LOC of 0.5. ?

Based on this avian reproduction effects may occur in seed eating birds for the following reasons:

1. The time between planting and emergence is expected to be one or two weeks. However, the avian reproduction study is not designed to determine the length of time needed to cause an effect. In fact many scientists believe that the current protocol, which allows 10 weeks of treated feed before the egg laying, is too long. They believe that this allows the parental birds physiology time the adjust the poisoning effect (Hill, E.F., and Turner, L. pers. comm). Therefore, masking more dramatic effects. Two weeks exposure may be adequate to cause the same effects provided it occurs at a critical part of the reproducing process. Difenconazole appears to make the birds ill enough to lower food consumption. The longer feed period before the onset of egg laying may allow for physiological adjustment to difenconazole. These effects would not be seen in the dietary LC50 study because it does not measure effected items, such as, egg production, embryo viability, and offspring survival (EPA guidelines 71-2).

2. Avian reproduction studies only address two species of 683 species in North America (Dunning 1984). Because there are so many species the surrogate species are not expected to have the lowest or the highest sensitivity to a difenconazole. Therefore, EEB expects some species to be more sensitive than the surrogate species.

3. In addition to differences in sensitive, birds smaller than the surrogate species eat a higher percentage of their body weight than larger birds (Kenaga 1973). Therefore, they would be expected to ingest more poison than the surrogate species relative to their body weight. Generally speaking seed eating birds are gallinaceous or passerines. The passerines are approximately half of the birds in North America. Most are smaller than the bobwhite quail (178g) (Dunning 1984).

4. Wild birds are expected use more energy and eat more than test birds.

4.1 Wild birds are expected to fly more than walk as do test birds in cages.

4.2 Wild birds have to escape predators.

4.3 Wild birds have to search for food.

4.4 Wild birds may have some illness or parasite.

4.5 Young birds which are growing faster than adults need more food.

Therefore, they would acquire more food and receive more poison over a given time period than the test bird.

5. Small grains also present an opportunity for foraging. They are only planted a half-inch deep and at a rate of 13,000, 14,000 and 18,000 seeds per acre for barley, oats and triticale, respectively (Petrie, R. pers. comm.). Seeds are expected to be available to the birds because:

- 5.1 Seeds will be spilled on the soil surface when the planters are lifted,
- 5.2 Seeds will inadvertently not get covered,
- 5.3 Seeds will be uncovered by wind, rain, and animals,
- 5.4 Birds searching techniques will uncover seeds.

6. Newly emerged plants would also be expected to be contaminated. If the mass of the seed had only increased 1.8 times it would still provide a risk quotient that would exceed a LOC of one. This scenario assumes no degradation in the one to two week period. Waterfowl, particularly, geese are known to feed heavily on grass (Martin et al. 1951). "Green shoots of winter wheat, rye, and legumes are also important foods for Canadas and snow geese in some localities (Linduska, 1964)". Also, the seed coat in most cases is relatively intact.

In summary avian reproduction is a concern for the 3 or 4 weeks after planting. The seed eating birds would be expected to be the most a risk.

101.3 Endangered Species Considerations

Based on the above discussion, an avian reproduction risk is assumed for endangered avian species. A review of the EPA endangered species database (see attached listing for each crop) indicates a number of endangered birds are found in counties with grow barley, oats and triticale. Because this is a seed treatment only seed eating birds would be expected to be exposed at high concentrations. Therefore, non-seed eaters were deleted from the list using Matthews (1990) and Ehrlich et al. (1988). Of those species most at risk are those with a high percentage of seeds in their diet. Of the birds on the attached list the Attwater's prairie chicken (*Tympanuchus cupido attwateri*), masked bobwhite quail (*Colinus virginianus ridgwayi*), and San Clemente sage sparrow (*Amphispiza belli clementeae*) seed are a large portion of their diet. Notice also the attached list is actually three lists one for each crop. Each crop list gives the state, number of acres of crop land by county. The exception to this is the Aleutian Canada goose (*Branta canadensis leucopareia*) which would be expected to eat small grains and the newly emerged plants (Linduska, 1964). Another consideration is that wheat is allowed at this time and it has a much greater use than any of these three crops.

In addition to these avian species feeding and reproduction effects are expected for endangered mammal especially small seed eating mice, voles, and rats as listed below:

1. Pacific pocket mouse (*Perognathus longimembris pacificus*)
2. Florida salt marsh Vole (*Microtus pennsylvanicus dukecampbelli*)
3. Alabama beach mouse (*Peromyscus polionotus ammobates*)
4. Choctawatchee beach mouse (*Peromyscus polionotus allopshys*)
5. Giant kangaroo rat (*Dipodomys ingens*)
6. Fresno kangaroo rat (*Dipodomys nitratoideis exilis*)
7. Amargosa vole (*Microtus californicus scirpensis*)
8. Salt marsh harvest mouse (*Reithrodontomys raviventris*)
9. Tipton kangaroo rat (*Dipodomys nitratoideis nitratoideis*)
10. Stephens' kangaroo rat (*Dipodomys stephensi*)

These species are found in counties where barley and oats grow.

101.4 Adequacy of Toxicity Data

The following requirements have not been fulfilled. The following is a list of those studies:

- 71-4(a) and 71-4(b) Avian Reproduction
for both Mallard Duck and Bobwhite Quail
- 71-1(b) Acute Avian Oral, Mallard Duck (Typical End-Use Product)
- 71-2(a) Acute Avian Dietary, Quail (Typical End-Use Product)
- 71-2(b) Acute Avian Dietary, Mallard (Typical End-Use Product)
- 72-4(a) Fish early-life stage
- 72-4(b) Daphnia life-cycle
- 122-2 Aquatic plant growth with two species (*Lemna gibba* and *Selenastrum capricornutum*)

The avian reproduction studies would be of high value if the problems in the first study happens to mask the ability to detect effects at lower concentrations. However, the risk assessment shows at the expected concentration the level of concern has been exceeded. Hence, a second study may increase the risk quotient but in significantly.

Avian acute studies are also of high value. They are needed to determine if the product is more toxic than the technical grade material. The mammalian study shows there is more than a two fold difference. To accurately determine is necessary to complete the risk assessment.

The aquatic data requirements have not changed since Hitch's review. the following was excerpted from his review:

"Currently we do not know how persistent difenoconazole is in the aquatic environment. We must, therefore, presume that it is persistent. However, as was stated earlier, the potential for difenoconazole reaching surface water is low, so widespread exposure to aquatic organisms is not expected. This gives a low value added to daphnia life-cycle and fish early life stage studies. These studies are not required for the seed treatment use. For future proposed uses and aquatic organisms, these chronic tests may be required."

Because difenoconazole is a fungicide and has a water solubility greater than 10 ppm (difenococazole water solubility is 3300 ppm) it is EEB's policy to require aquatic plant testing (122-2) with freshwater green algae *Selenastrum capricornutum* and *Lemna gibba*. The lack of plants in an ecosystem would be expected to lower the productivity of that system. Plants provide the mechanism for capturing energy for the system. The less energy the less the plants and, therefore, the less food for the fauna. Therefore, these studies are of high value.

102 Adequacy of Labeling

The proposed labeling (see below) follows guideline requirements.

"This product is toxic to fish and other aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters or rinsate."

"If treated seed is spilled outdoors or in areas accessible to birds, promptly clean up or bury to prevent ingestion."

103 Conclusions

Summary of Risk

EEB has reviewed the proposed uses for difenoconazole. Based on the tests with the technical product, acute risk is minimal for most fauna except endangered species. However, mammalian studies indicate that the toxicity is higher for the product. We do not know the bird toxicity or risk of the product. If the acute toxicity changes at the same rate as it did with the mammal acute toxicity studies still minimum risk is indicated. Whether birds or mammals react the same toxicologically to difenoconazole is unknown at this time. Therefore, the risk from the product is unknown. Section 101.4 lists, among other studies, the necessary acute birds studies.

Minimum risk is expected for the fish and aquatic invertebrates. This compound is highly toxic. The low application is what prevents risk for these seed treatment uses. Because there is no

known route of degradation for this compound, the EEC was derived assuming difenoconazole was stable. The Environmental Fate and Groundwater Branch requires only hydrolysis studies for seed treatment chemicals. Because difenoconazole was found to not hydrolyze, there is no known route of degradation for this compound. This greatly increases the hazard to aquatic organisms due to possible spills (Hitch, 1994). If a spill would occur EPA would be able to estimate the degradation period or the potential size of kill area. The instantaneous concentration of the spill is expected to result in concentrations that exceed the aquatic toxicity values by several orders of magnitude. Without degradation only dilution would change expected exposure.

There is a potential risk to the bird reproduction. The concentration on the treated seeds exceeds the NOELs. However, the present studies may not be accurate and do not fulfill guideline requirements. Potentially the NOEL may be lower. Based on this, both the mallard duck and bobwhite quail are still outstanding (71-4) (a) (b). The following two items are expected to reduce the risk for some species:

1. The exposure period is only expected to be 3 or 4 weeks.
2. Because this is a seed treatment, only seed eating birds would be expected to be exposed for the full period.

The risk to aquatic plants has not been assessed because of the lack of data. The following studies are needed:

Aquatic plant testing (122-2) with freshwater green algae
Selenastrum capricornutum and *Lemna gibba*

Endangered species are expected to be at risk. Based on their food preferences and location (they are found in counties where oats or barley are grown) the following endangered species are at risk:

Birds

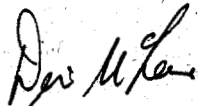
1. Attwater's prairie chicken (*Tympanuchus cupido attwateri*)
2. Masked bobwhite quail (*Colinus virginianus ridgwayi*)
3. Aleutian Canada goose (*Branta canadensis leucopareia*)
4. San Clemente sage sparrow (*Amphispiza belli clementeae*)

Mammals

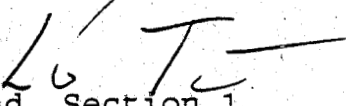
1. Pacific pocket mouse (*Perognathus longimembris pacificus*)
2. Florida salt marsh Vole (*Microtus pennsylvanicus dukecampbelli*)
3. Alabama beach mouse (*Peromyscus polionotus ammobates*)
4. Choctawatchee beach mouse (*Peromyscus polionotus allophrys*)
5. Giant kangaroo rat (*Dipodomys ingens*)

3. Alabama beach mouse (*Peromyscus polionotus ammobates*)
4. Choctawatchee beach mouse (*Peromyscus polionotus allophrys*)
5. Giant kangaroo rat (*Dipodomys ingens*)
6. Fresno kangaroo rat (*Dipodomys nitratoides exilis*)
7. Amargosa vole (*Microtus californicus scirpensis*)
8. Salt marsh harvest mouse (*Reithrodontomys raviventris*)
9. Tipton kangaroo rat (*Dipodomys nitratoides nitratoides*)
10. Stephens' kangaroo rat (*Dipodomys stephensi*)

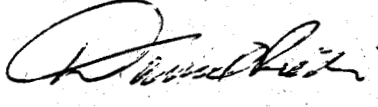
(see the attached state and county list of these endangered species for each crop).

Dennis J. McLane, Wildlife Biologist 
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Date: 10-4-96


Les W. Touart, Acting Head, Section 1
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

10.4.96
Date:


Daniel D. Rieder
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Date: 10.7.96

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Oats and Birds

Updated through: October 1, 1992 Tuesday 09/10/96 09:44

Page: 1

PIMA AZ Barley for grain, Harvested ACREAGE = 174

SPECIES	GROUP	STATUS	KNOWN
BOBWHITE, MASKED	BIRD	E	KNOWN

LOS ANGELES CA Barley for grain, Harvested ACREAGE = 3378

SPECIES	GROUP	STATUS	KNOWN
SPARROW, SAN CLEMENTE SAGE	BIRD	T	KNOWN

Barley and Birds

GLENN CA Oats for grain, Harvested ACREAGE = 587

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	KNOWN

KINGS CA Oats for grain, Harvested ACREAGE = 1044

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

IMPERIAL CA Oats for grain, Harvested ACREAGE = 32

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

MENDOCINO CA Oats for grain, Harvested ACREAGE = 286

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

MERCED CA Oats for grain, Harvested ACREAGE = 6919

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

SACRAMENTO CA Oats for grain, Harvested ACREAGE = 1824

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

SAN DIEGO CA Oats for grain, Harvested ACREAGE = 230

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

SAN JOAQUIN CA Oats for grain, Harvested ACREAGE = 3126

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

SAN LUIS OBISPO CA Oats for grain, Harvested ACREAGE = 975

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

SANTA BARBARA CA Oats for grain, Harvested ACREAGE = 1188

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

SISKIYOU CA Oats for grain, Harvested ACREAGE = 1803

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE

SOLANO CA Oats for grain, Harvested ACREAGE = 1329

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	KNOWN

STANISLAUS CA Oats for grain, Harvested ACREAGE = 4667

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	KNOWN

SUTTER CA Oats for grain, Harvested ACREAGE = 869

SPECIES	GROUP	STATUS	KNOWN
GOOSE, ALEUTIAN CANADA	BIRD	T	KNOWN

YOLO CA Oats for grain, Harvested ACREAGE = 1456

SPECIES	GROUP	STATUS	KNOWN
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GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE
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BENTON OR Oats for grain, Harvested ACREAGE = 1466

SPECIES	GROUP	STATUS	KNOWN
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GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE
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DOUGLAS OR Oats for grain, Harvested ACREAGE = 685

SPECIES	GROUP	STATUS	KNOWN
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GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE
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LANE OR Oats for grain, Harvested ACREAGE = 1744

SPECIES	GROUP	STATUS	KNOWN
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GOOSE, ALEUTIAN CANADA	BIRD	T	POSSIBLE
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REFUGIO TX Oats for grain, Harvested ACREAGE = 62

SPECIES	GROUP	STATUS	KNOWN
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PRAIRIE-CHICKEN, ATTWATER'S GREATER	BIRD	E	KNOWN
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WASHINGTON TX Oats for grain, Harvested ACREAGE = 89

SPECIES	GROUP	STATUS	KNOWN
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PRAIRIE-CHICKEN, ATTWATER'S GREATER	BIRD	E	KNOWN
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BARLEY AND MAMMALS

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Page: 1

ALAMEDA CA Barley for grain, Harvested ACREAGE = 638

SPECIES	GROUP	STATUS	KNOWN
MOUSE, SALT MARSH HARVEST	MAMMAL	E	KNOWN

FRESNO CA Barley for grain, Harvested ACREAGE = 19281

SPECIES	GROUP	STATUS	KNOWN
RAT, FRESNO KANGAROO	MAMMAL	E, CH	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN

KERN CA Barley for grain, Harvested ACREAGE = 20597

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, TIPTON KANGAROO	MAMMAL	E	KNOWN

KINGS CA Barley for grain, Harvested ACREAGE = 13119

SPECIES	GROUP	STATUS	KNOWN
RAT, FRESNO KANGAROO	MAMMAL	E, CH	POSSIBLE
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, TIPTON KANGAROO	MAMMAL	E	KNOWN

LOS ANGELES CA Barley for grain, Harvested ACREAGE = 3378

SPECIES	GROUP	STATUS	KNOWN
MOUSE, PACIFIC POCKET	MAMMAL	E	KNOWN

MADERA CA Barley for grain, Harvested ACREAGE = 3397

SPECIES	GROUP	STATUS	KNOWN
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RAT, FRESNO KANGAROO MAMMAL E,CH POSSIBLE

MERCED CA Barley for grain, Harvested ACREAGE = 6902

SPECIES	GROUP	STATUS	KNOWN
RAT, FRESNO KANGAROO	MAMMAL	E,CH	POSSIBLE
RAT, GIANT KANGAROO	MAMMAL	E	POSSIBLE

MONTEREY CA Barley for grain, Harvested ACREAGE = 23640

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	POSSIBLE

RIVERSIDE CA Barley for grain, Harvested ACREAGE = 5468

SPECIES	GROUP	STATUS	KNOWN
RAT, STEPHENS' KANGAROO	MAMMAL	T	KNOWN

SAN BENITO CA Barley for grain, Harvested ACREAGE = 7612

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN

SAN BERNARDINO CA Barley for grain, Harvested ACREAGE = 382

SPECIES	GROUP	STATUS	KNOWN
RAT, STEPHENS' KANGAROO	MAMMAL	T	POSSIBLE
VOLE, AMARGOSA	MAMMAL	E,CH	KNOWN

SAN LUIS OBISPO CA Barley for grain, Harvested ACREAGE = 24964

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, MORRO BAY KANGAROO	MAMMAL	E,CH	KNOWN

SANTA BARBARA CA Barley for grain, Harvested ACREAGE = 3511

SPECIES	GROUP	STATUS	KNOWN
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SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN

SOLANO CA Barley for grain, Harvested ACREAGE = 6378

SPECIES	GROUP	STATUS	KNOWN
MOUSE, SALT MARSH HARVEST	MAMMAL	E	KNOWN

SPECIES	GROUP	STATUS	KNOWN
MOUSE, SALT MARSH HARVEST	MAMMAL	E	KNOWN

TULARE CA Barley for grain, Harvested ACREAGE = 14866

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, TIPTON KANGAROO	MAMMAL	E	KNOWN

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, TIPTON KANGAROO	MAMMAL	E	KNOWN

OATS AND MAMMALS

Updated through: October 1, 1992 Friday 09/20/96 09:41

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BALDWIN AL Oats for grain, Harvested ACREAGE = 2712

SPECIES	GROUP	STATUS	KNOWN
MOUSE, ALABAMA BEACH	MAMMAL	E, CH	KNOWN
MOUSE, PERDIDO KEY BEACH	MAMMAL	E, CH	KNOWN

FRESNO CA Oats for grain, Harvested ACREAGE = 1484

SPECIES	GROUP	STATUS	KNOWN
RAT, FRESNO KANGAROO	MAMMAL	E, CH	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN

KERN CA Oats for grain, Harvested ACREAGE = 227

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, TIPTON KANGAROO	MAMMAL	E	KNOWN

KINGS CA Oats for grain, Harvested ACREAGE = 1044

SPECIES	GROUP	STATUS	KNOWN
RAT, FRESNO KANGAROO	MAMMAL	E, CH	POSSIBLE
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, TIPTON KANGAROO	MAMMAL	E	KNOWN

MADERA CA Oats for grain, Harvested ACREAGE = 2435

SPECIES	GROUP	STATUS	KNOWN
RAT, FRESNO KANGAROO	MAMMAL	E, CH	POSSIBLE

MERCED CA Oats for grain, Harvested ACREAGE = 6919

SPECIES	GROUP	STATUS	KNOWN
RAT, FRESNO KANGAROO	MAMMAL	E, CH	POSSIBLE
RAT, GIANT KANGAROO	MAMMAL	E	POSSIBLE

RUN No. 1 FOR difenocoazole INPUT VALUES

RATE (#/AC) ONE (MULT)	APPLICATIONS NO. - INTERVAL	SOIL KOC	SOLUBILITY (PPM)	% SPRAY DRIFT	INCRP DEPTH (IN)
.020 (.020)	1 1	2185.0	3300.0	.0	1.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
.00	2	N/A	.00-	.00	.00 *****

GENERIC EECs (IN PPT)

PEAK GEEC	AVERAGE 4 DAY GEEC	AVERAGE 21 DAY GEEC	AVERAGE 56 DAY GEEC
140.05	132.90	103.96	77.01

MONTEREY CA Oats for grain, Harvested ACREAGE = 547

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	POSSIBLE

RIVERSIDE CA Oats for grain, Harvested ACREAGE = 2042

SPECIES	GROUP	STATUS	KNOWN
RAT, STEPHENS' KANGAROO	MAMMAL	T	KNOWN

SAN BENITO CA Oats for grain, Harvested ACREAGE = 378

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN

SAN BERNARDINO CA Oats for grain, Harvested ACREAGE = 108

SPECIES	GROUP	STATUS	KNOWN
RAT, STEPHENS' KANGAROO	MAMMAL	T	POSSIBLE
VOLE, AMARGOSA	MAMMAL	E, CH	KNOWN

SAN DIEGO CA Oats for grain, Harvested ACREAGE = 230

SPECIES	GROUP	STATUS	KNOWN
MOUSE, PACIFIC POCKET	MAMMAL	E	KNOWN
RAT, STEPHENS' KANGAROO	MAMMAL	T	KNOWN

SAN LUIS OBISPO CA Oats for grain, Harvested ACREAGE = 975

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, MORRO BAY KANGAROO	MAMMAL	E, CH	KNOWN

SANTA BARBARA CA Oats for grain, Harvested ACREAGE = 1188

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN

SANTA CLARA CA Oats for grain, Harvested ACREAGE = 120

SPECIES	GROUP	STATUS	KNOWN
MOUSE, SALT MARSH HARVEST	MAMMAL	E	KNOWN

SOLANO CA Oats for grain, Harvested ACREAGE = 1329

SPECIES	GROUP	STATUS	KNOWN
MOUSE, SALT MARSH HARVEST	MAMMAL	E	KNOWN

SONOMA CA Oats for grain, Harvested ACREAGE = 2395

SPECIES	GROUP	STATUS	KNOWN
MOUSE, SALT MARSH HARVEST	MAMMAL	E	KNOWN

TULARE CA Oats for grain, Harvested ACREAGE = 2739

SPECIES	GROUP	STATUS	KNOWN
RAT, GIANT KANGAROO	MAMMAL	E	KNOWN
RAT, TIPTON KANGAROO	MAMMAL	E	KNOWN

LEVY FL Oats for grain, Harvested ACREAGE = 132

SPECIES	GROUP	STATUS	KNOWN
VOLE, FLORIDA SALT MARSH	MAMMAL	E	KNOWN

WALTON FL Oats for grain, Harvested ACREAGE = 375

SPECIES	GROUP	STATUS	KNOWN
MOUSE, CHOCTAWHATCHEE BEACH	MAMMAL	E, CH	KNOWN

RUN No. 1 FOR difenocoazole INPUT VALUES

RATE (#/AC) ONE (MULT)	APPLICATIONS NO.-INTERVAL	SOIL KOC	SOLUBILITY (PPM)	% SPRAY DRIFT	INCRP DEPTH (IN)
.020 (.020)	1 1	2185.0	3300.0	.0	1.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
.00	2	N/A	.00-	.00	.00 *****

GENERIC EECs (IN PPT)

PEAK GEEC	AVERAGE 4 DAY GEEC	AVERAGE 21 DAY GEEC	AVERAGE 56 DAY GEEC
140.05	132.90	103.96	77.01